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Assessment of impact of information booklets on use of healthcare services: randomised controlled trial

David Heaney, Sally Wyke, Philip Wilson, Rob Elton, Philip Rutledge

Abstract

Objectives To investigate the effect of patient information booklets on overall use of health services, on particular types of use, and on possible interactions between use, deprivation category of the area in which respondents live, and age. To investigate the possibility of a differential effect on health service use between two information booklets.

Design Randomised controlled trial of two patient information booklets (covering the management and treatment of minor illness).

Setting 20 general practices in Lothian, Scotland.

Participants Random sample of patients from the community health index ($n = 4878$) and of those contacting out of hours services ($n = 4530$) in the previous 12 months in each of the study general practices.

Intervention Booklets were posted to participants in intervention groups (3288 were sent *What Should I Do?*; 3127 were sent *Health Care Manual*). Patients randomised to control group (2993) did not receive a booklet.

Main outcome measures Use of health services audited from patients' general practice notes in 12 months after receipt of booklet.

Results Receipt of either booklet had no significant effect on health service use compared with a control group. However, nine out of ten matched practices allocated to receive *Health Care Manual* had reduced consultation rates compared with matched practices allocated to *What Should I Do?*

Conclusion Widespread distribution of information booklets about the management of minor illness is unlikely to reduce demand for health services.

Introduction

There is a general perception among healthcare professionals that increasing demand for health services is caused partly by lack of knowledge about self management of minor illness. This view of help seeking behaviour, which could be called "the information deficit model," suggests that provision of information about the management and treatment of minor illness should result in reduced use of health services. An alternative view of help seeking behaviour sees individuals responding reflexively to symptoms on the basis of information from a wide range of both for-

mal and informal sources and using their own experience of symptoms and of previous care.¹⁻⁶ This view, which could be called "the contingent model," suggests that the provision of information is unlikely to result in reduced use of services because pathways to professional care are contingent on a wide range of other factors. Information alone, while it may be valued by patients, is unlikely to be enough to change behaviour.

Several information booklets on minor illness are currently used throughout the United Kingdom. The *What Should I Do?* booklet was part of a patient education programme implemented in the Netherlands in 1993. The booklet outlines 40 common health problems and provides information on when to consult a doctor and on self care, when appropriate. In the publicity accompanying the launch of the booklet in the United Kingdom the publishers claimed that the booklet would reduce unnecessary consultations.⁷ Two studies were undertaken in the United Kingdom around the time of the launch of the booklet,^{8,9} but until recently no formal evaluation of the booklet has been published.¹⁰ Another information booklet, *Health Care Manual*, was developed by a general practitioner and practice nurse in Dunkeld, Scotland. It outlines about 50 common health problems and also provides information about keeping healthy. The booklet was successfully distributed in the practice, but to date no formal evaluation has taken place. The two booklets are similar in approach but differ in terms of design.

Previous research on the impact of information booklets on patient behaviour has been restricted to one general practice,^{11,12} specific health problems,¹³⁻¹⁶ or children's symptoms.¹⁷⁻¹⁹ A randomised controlled trial of the effect of Baby Check (an illness scoring system) showed that distribution to an unselected group of mothers did not affect use of health services.²⁰ A quasi-experimental evaluation of the distribution of *What Should I Do?* in one health authority suggested that possession of the booklet was associated with more "appropriate" self care and self referral behaviour, as assessed by responses to hypothetical illness scenarios.¹⁰

We carried out a randomised controlled trial of the impact of the provision of two patient information booklets on the management and treatment of minor illness on subsequent use of health services over 12 months. Because previous theory and research has shown that the simple "information deficit" model is

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unlikely to reduce the likelihood of consultations,¹⁻⁶ we suspected that the provision of such booklets would not impact on overall use of health services. However, information booklets might influence use of particular types of services, such as general practitioner consultations for minor illness and out of hours consultations. We also suspected that there may be interactions between use of services, deprivation category of area of residence, and age. We designed the study and analysis to allow a comparison of the possible differential impact of the two booklets on use of health services.

Methods

Protocol

All practices in the Lothian Health Board area (excluding practices in the Midlothian GP locality) and all patients aged over 1 year registered in participating practices were eligible. Two samples were drawn from each practice. One sample was from the community health index (the general practice list) and one from the database of users of out of hours services 12 months before sampling. Three practices selected for the study did not belong to the out of hours central call handling system so we could not obtain an out of hours sample for these practices. Practices alerted the research team to any deaths or any names and addresses that were incorrect. We targeted a small proportion of patients in each practice (about 1 in 25 patients), so the probability of contamination was low. In an attempt to reduce this problem further, we sampled only one patient per household.

The primary outcome measure was use of health services in the 12 months after receipt of the information booklet. For the year before and after the intervention, a team of nurses counted the number of health service contacts recorded in patients' general practice medical records. The nurses noted the type of each contact and judged whether the contact was for a minor ailment that could have been dealt with by the patient without the need to consult a general practitioner. The definition was derived from the

contents pages of the booklets and after discussion with nurses in training for the exercise.

Analysis

Power calculations were based on the assumption that receipt of an information booklet would be associated with a reduction in annual consultation rate. We estimated the mean (SD) consultation rate as 4.2 (3.9), which meant that we required 2081 patients in each group to give a 95% power to detect a 12.5% reduction in mean attendance. Our target was therefore to allocate 2000 patients to *What Should I Do?*, 2000 to *Health Care Manual*, and 2000 to the control group.

We used linear regression to estimate the effects of receipt of an information booklet on overall service use, on types of service use, and on possible interactions between deprivation category of the area in which respondents lived and age. Because health service use is known to be affected by previous health service use,⁶ consultation rates in the 12 months before the intervention were included in all regression models as an independent variable. The residuals from these regressions were found to be quite symmetrical, and this, combined with the large sample size, justified the use of approximate normal confidence limits.

To compare the differential effect of receipt of *What Should I Do?* compared with *Health Care Manual* we matched the 20 participating practices by deprivation, list size, and area. We used linear regression in each practice separately and compared results between matched pairs.

Assignment

All randomisation was done with computer generated random numbers. We selected 20 general practices at random and stratified those who agreed to take part according to deprivation category (high, medium, low),²¹ list size (large, medium, small) and area (Edinburgh City, West Lothian, East Lothian). Subsequently, we stratified all other practices in the sample to match recruited practices according to the same criteria, randomly sampled them, and requested participation until we found a match.

Each matched pair of practices was randomly allocated to receive one of the two booklets. Individual patients were randomised to either intervention or control groups. All selected patients (or parents when the selected individual was aged under 16 years) were invited to participate in the study and to consent to their medical records being examined. They received a booklet if they were in one of the intervention groups. Consent was by opt out, as patients had to complete a return slip if they did not want to take part in the study. The study was approved by the local ethics committee. The nurses did not know whether the patient was in the intervention or control groups. Figure 1 summarises the randomisation process.

Results

Twelve of the original 20 practices approached agreed to participate. A further eight practices were sampled and six agreed at this stage. A final two practices were sampled and both agreed to take part, achieving the 10 matched pairs required. The final response rate from general practices was therefore 20/30 (67%).

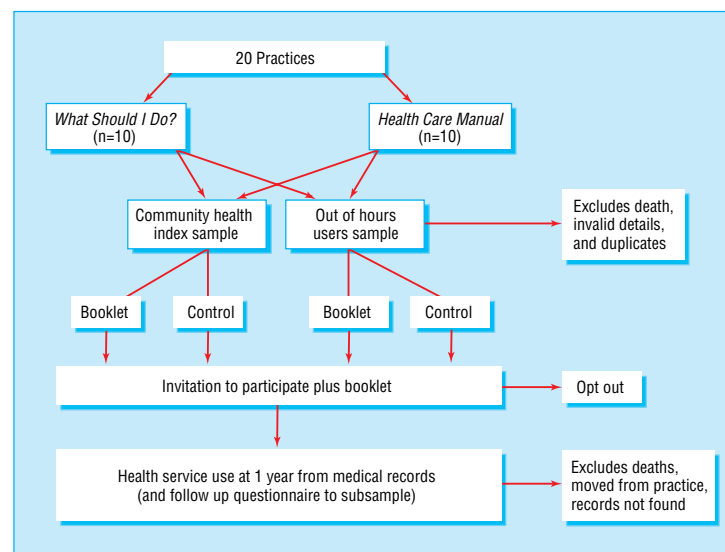


Fig 1 Randomisation process for practices in study. Groups were matched by deprivation, list size, and area

Figure 2 show the flow of patients through the study and shows loss to follow up at each stage. The final number of records was 4953, 1702 patients in the *What Should I Do?* group, 1688 in the *Health Care Manual* group, and 1563 in the control group.

The table shows mean overall rates of use of health services in the year before and the year after the intervention for those receiving a booklet compared with those in the control group. Mean rates in the community health index sample were identical before and after the intervention. There was a systematic decline in the number of contacts in the out of hours sample in the second year. This was due to regression to the mean: our sample was drawn from users in the first year of study, and some of these users will have had an episode in the year before the intervention but not in the second year. The expected decline was of similar magnitude for intervention and control groups. The 95% confidence intervals from ordinary linear regression of the numbers of each type of consultation show receipt of an information booklet did not have a significant effect on health service use. We repeated these analyses for each booklet against controls separately and found no significant effect on overall health service use for either sample in either of these analyses compared with controls.

We repeated the analysis two specific types of health service use: general practitioner consultations for minor illness and out of hours consultations. Receipt of an information booklet had no effect on either type of consultation for either sample. Analyses of the interactions between the effects of age and deprivation category and receipt of an information booklet on health service use showed no significant associations.

We used linear regression for each practice separately to estimate the size of any effect of the booklet for all consultations in the community health index sample. For eight of ten practices allocated to *Health Care Manual* the estimates were negative compared with four estimates for the practices allocated to *What Should I Do?* Nine of the ten *Health Care Manual* estimates were lower in value than their matched *What Should I Do?* estimates.

What is already known on this topic

One view of help seeking behaviour is that increasing demand for health services is associated with a lack of knowledge in the self management of minor illness

An alternative view sees individuals responding reflexively to symptoms on the basis of information and advice from a wide range of sources and using their own experiences

What this study adds

The lack of effect on health service use indicates that widespread postal distribution of information booklets about the management of minor illness is unlikely to reduce demand for health services

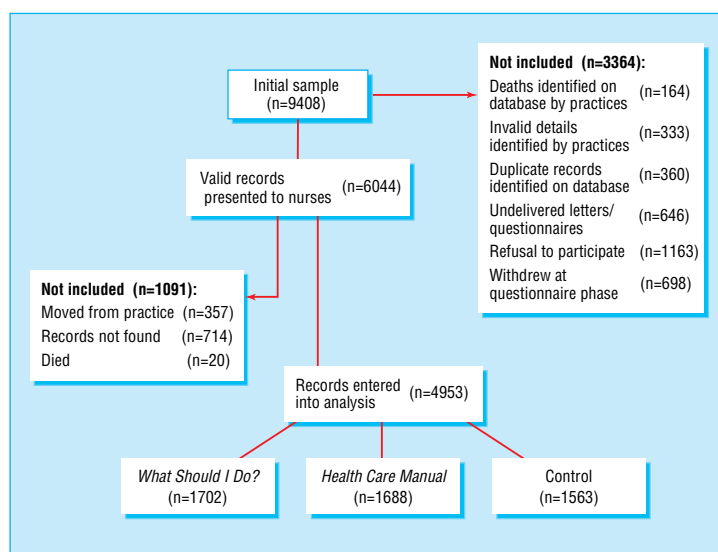


Fig 2 Flow of participants through study

Discussion

This large study showed that overall, patient information booklets have no effect on use of health services. Our outcome measure was use of health services audited from general practice notes, without follow up (by, for example, auditing hospital records). We also sent patients a questionnaire about the booklets eight weeks after distribution. The intervention in this study was minimal, consisting of simple postal distribution of two information booklets, which meant that practices did not need to commit much time or effort to the study. A criticism of this approach is that postal distribution without re-enforcement of the message from health professionals may be less likely to change behaviour. Other forms of distribution would target users of services only, would be difficult to randomise, and would require a level of commitment from health professionals which might be difficult to implement in practice and might bias results. As the drop out rate in the study was higher than we expected we did not achieve the estimated 2000 in each group to achieve 95% power, although this is unlikely to have had an important effect on the results presented.

Patients are exposed to a lot of information about the management of minor illness from government, professional organisations, and the media. Provision of such information may result in lower demand for primary care services. The two information booklets were designed to give advice on “more appropriate” use of

Mean rates of health service (primary care) use in year before and year after intervention (95% confidence interval for estimated effect of booklet adjusted for baseline)

	Book		Control		Difference (95% CI)
	Before	After	Before	After	
Community health index					
Total contacts	4.19	4.20	3.95	3.91	0.14 (−0.18 to 0.45)
Contacts for minor illness	1.13	1.09	1.06	1.07	0.03 (−0.17 to 0.10)
Out of hours contacts	0.13	0.11	0.11	0.13	−0.02 (−0.06 to 0.01)
Out of hours					
Total contacts	8.53	6.57	9.02	6.65	0.22 (−0.31 to 0.75)
Contacts for minor illness	2.24	1.74	2.43	1.84	0.02 (−0.25 to 0.29)
Out of hours contacts	0.13	0.11	0.11	0.13	−0.03 (−0.20 to 0.14)

primary care services. As hypothesised, the provision of information booklets did not have any effect on overall use of health services or influence consultations for minor illness and out of hours consultations. While neither booklet had a significant effect on health service use compared with no booklet, nine out of ten matched practices allocated to receive *Health Care Manual* had relatively reduced consultation rates compared with practices allocated to *What Should I Do?* Nevertheless, the lack of effect on health service use of either booklet, either together or alone, compared with controls indicates that widespread postal distribution of information booklets about the management of minor illness is unlikely to reduce demand for health services. If reduction in demand for services is the aim, then more sophisticated interventions are required which build on the available evidence surrounding patient behaviour.

The patient information booklet *What Should I Do?* was written by E van der Does and R G Metz (UK Medical Advisers Dr R Hughes and Dr K Jan-Mohamed) and published by RTFB Publishing. It is available on line at www.whatshouldido.com. The patient information booklet *Health Care Manual* was designed and written by Dr J Silbern and W Latham.

Contributors: All authors contributed to the conception and design of the study. DH oversaw the conduct of the trial, undertook analysis and interpretation of resulting data, and drafted and revised the paper. SW and PW contributed to the interpretation of data and revised the paper. RE undertook analysis and interpretation of data and contributed to the revision of the paper. PR contributed to the revision of the paper. Fiona Bell administered the postal survey of patients. DH is guarantor of the paper.

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Competing interests: None declared.

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The researchers who conducted this study used a form of "opt out" consent for participants. We asked two commentators whether they think this practice is acceptable in this study and others like it, when there is no risk of harm to participants.

Commentary: What's wrong with opting out?

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No one would argue against the principle of seeking valid and informed patient consent to medical interventions, or against seeking a similarly high standard of informed consent to active participation in research. Although we know that patients' decisions are strongly influenced by the quality of information they are given and the way the options are portrayed to them, the idea of "informed consent" undeniably embodies the ideal. It implies respect and partnership. Consent based on thorough and detailed disclosure of all relevant implications is essential for any physical intervention, especially those entailing risk or inconvenience for the patient (and anything which is not demonstrably in the best interests of a person with mental incapacity).

Circumstances occur, however, in which patients are not actively involved in the research and questions arise

about the extent to which they must be individually contacted. When there is no touching, no risk, no treatment tested, as when research consists of extraction of data from records, is specific consent essential? The General Medical Council's guidelines on confidentiality say no and rely on the concept of "presumed consent" or "opting out."¹ It is increasingly accepted that patients' rights to privacy are still respected if they are made aware in general terms about use of data for research. If they fail to exempt themselves, patients are assumed to have given tacit consent. They can refuse to have their data used—even anonymously—by opting out. It just requires a bit of effort, and researchers rely heavily on the inertia factor.

In this project, patients were given the choice of exempting their records from research by returning a

slip. Of the initial sample of 9408 patients, 1163 patients opted out and 698 withdrew later. Were anyone's rights really compromised? Most of us do not make the effort to opt out, mainly because presumed consent is used only when there is little or no direct implication for us. The moral basis is the assumption that most people—if individually asked—would want to help.

Arguably, questions now arise partly because a more disappointing presumption is prevalent. The presumption is that people using the NHS have rights

but no obligations to allow their information to be used to improve the system. It is symptomatic of how the notions of patient responsibility or presumption of altruism risk becoming deeply unfashionable in the politically correct culture of “rights.”

These are the views of the author and not necessarily those of the BMA.

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Commentary: Public opinion may force researchers to seek “opt in” consent for all studies

Tom Wilkie

What is informed consent for? Historically, there has been a clear line of development since the concept was first articulated a century ago in regulations from the Prussian Ministry of Health. The stipulation that researchers should seek informed consent followed a scandal in which people had been infected with syphilis, without even knowing that they had been participating in research. Informed consent was a fundamental article of the Nuremberg Code, which formed part of the final judgment at the Nazi doctors' trial. Surprisingly, from today's perspective, the Nuremberg Code and its requirement for consent were not seen as relevant in British or American research practice in the years after the second world war. It was only after revelations of abuse by Maurice Pappworth and Henry Beecher in the United Kingdom and the United States that formal safeguards were introduced, leading in the United Kingdom to the system of research ethics committees that we have today.^{1,2}

Consent is part of that system of safeguards applying to research that might put human participants at risk of harm. In the case of the paper by Heaney et al the research being carried out was not even remotely likely to cause harm to any of the research participants. The project was intended to find out whether the provision of information would affect people's use of health services. So it is perfectly understandable that the research ethics committee decided that the normal procedure of consenting to participate was not needed and instead allowed an opt out process.

However, public attitudes in Britain towards medicine, science, and research are in a state of flux. One emerging element suggests that the traditional rationale for seeking consent may need to be supplemented. Under this new model consent would have to be sought not only as a protection against

harm, but as an acknowledgement that those who participate in research as volunteer “subjects” have a status equally worthy of respect as those who participate as researchers. The clearest expression of this is to be found in the Bristol inquiry's interim report on retention of organs.³ Some preliminary research sponsored by the Medical Research Council and the Wellcome Trust into public attitudes to DNA sample collections also revealed that seeking consent was seen as a mark of respect as well as, or even more than, a way of preventing harm.⁴

It is too early to be certain that social change will drive this new rationale for seeking consent, but if it does then even innocuous studies would require the full opt in, informed consent procedure in the future. I am advocating that we should not go down this route for two reasons: the cost and delay to research that would be involved; and the risk that embarking on such a route may take us into the same territory as US bioethics, with its heavy overemphasis on autonomy and respect for people at the expense of other virtues (such as the duty of care) or ethical principles that we might equally want to promote. I advocate, however, that researchers and their ethics committees think clearly about what informed consent is for and take care that their rationales keep step with public attitudes in what are confusing and changing times.

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